STATEMENT

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In Opposition to Connecticut Senate Bill 13

March 1, 2022

Position: PhRMA respectfully opposes Senate Bill 13 ("SB 13"). PhRMA believes that discussions about the affordability of drugs are important, but the intention of this bill is to penalize biopharmaceutical manufacturers for certain price increases, which could limit the availability of prescription options to Connecticut residents and also raises constitutional concerns. This bill also directs the Commissioner of Consumer Protection to design a wholesale prescription drug importation program for the importation of drugs from Canada. Such a proposal mischaracterizes importation as a tool to lower drug costs and disregards the inherent threats to patient safety associated with drug importation.

SB 13 would require a drug manufacturer to pay an 80% penalty on price increases greater than the consumer price index plus 2% annually. This limit on the price of patented products raises constitutional concerns. Further, this proposal focuses on manufacturers, ignoring the rest of the prescription drug supply chain, and does nothing to address what patients pay at the pharmacy counter.

Implementing price controls at a time when the industry has been tirelessly dedicated to finding treatments and vaccines for COVID-19 diverts industry resources elsewhere and risks current and future innovation. We are in a new era of medicine that is bringing revolutionary, innovative treatments, therapies, and cures to patients. This legislation does nothing to ensure affordability for patients when purchasing medicines, could limit patient access to needed medicines, and could negatively affect Connecticut's economy.

This legislation ignores that there are meaningful policies for addressing affordability without government price setting that could reduce treatment options.

PhRMA is increasingly concerned that the substantial rebates and discounts paid by pharmaceutical manufacturers, approximately $187 billion in 2020,[1] do not make their way to offsetting patient costs at the pharmacy counter. Patients need concrete reforms that will help lower the price they pay for medicines at the pharmacy, such as making monthly costs more predictable, making cost-sharing assistance count toward a plan's out-of-pocket spending requirements, and sharing negotiated savings on medicines with patients. These policies can be implemented without government price controls, which can reduce the options available to treat patients.

This legislation does not account for insurance benefit design issues that prevent discounts from flowing to patients, and SB 13 assumes incorrectly that the price a patient pays is determined solely by drug manufacturers.

This legislation singles out the biopharmaceutical industry and ignores the variety of stakeholders involved in determining what consumers ultimately pay for a medicine, including insurers, pharmacy benefit managers (PBMs), wholesalers, and the government. The important role that these entities play in determining drug coverage and patient out-of-pocket costs is overlooked by the requirements of this legislation. For example, PBMs and payers—which dictate the terms of coverage for medicines and the amount a patient ultimately pays—negotiate substantial rebates and discounts.

[1] https://www.drugchannels.net/2021/04/gross-to-net-bubble-update-net-prices.html

According to research from the Berkeley Research Group (BRG), rebates, discounts, and fees account for an increasing share of spending for brand medicines each year, while the share received by manufacturers has decreased over time. In 2020 manufacturers retained only 49.5% of brand medicine spending while members of the supply chain retained 50.5%.[2] Increased rebates and discounts have largely offset the modest increases in list prices and reflect the competitive market for brand medicines.

The growth of net prices, which reflects rebates and discounts, has been in line with or below inflation for the past five years. Specifically, brand medicine net prices decreased 2.9% in 2020.[3] This, of course, does not necessarily reconcile with what patients are feeling at the pharmacy counter, which is why looking at the whole system is so important. For example, despite manufacturers' rebates and discounts negotiated by health plans, nearly half of commercially insured patients' out-of-pocket spending for brand medicines is based on the medicine's list price rather than the negotiated price that health plans receive.[4]

Price controls on brand medicines raise constitutional concerns.

The price control in SB 13, effectuated through onerous penalties, raises constitutional concerns under the Supremacy Clause because it would restrict the goal of federal patent law, which is to provide pharmaceutical patent holders with the economic value of exclusivity during the life of a patent. Congress determined that this economic reward provides appropriate incentive for invention and Connecticut is not free to diminish the value of that economic reward. Specifically, in the case of *BIO v. District of Columbia,*[5] the U.S. Court of Appeals for the Federal Circuit overturned a District of Columbia law imposing price controls on branded drugs, reasoning that the law at issue conflicted with the underlying objectives of the federal patent framework by undercutting a company's ability to set prices for its patented products.

This legislation could chill innovation and harm Connecticut's economy.

SB 13 threatens to drastically reduce development of new medicines at a time of remarkable scientific promise, undermining U.S. global leadership in biopharmaceutical innovation. Government price setting diminishes the incentive for biopharmaceutical manufacturers to invest in the research and development of new medicines. By imposing significant penalties for sales of a prescription drug over a reference price, this legislation creates a price control on these medicines that could have the long-term effect of decreasing access to medications.

Inflation penalties could reduce companies' ability to continue to invest in R&D. The State would require such penalties even if substantial rebates are paid to commercial payers or Medicaid for the medicine dispensed. Companies rely on revenues from today's medicines to invest in tomorrow's treatments and cures. Yet the costs of drug development have continued to increase over the past several decades – due to factors including increased clinical trial complexity, larger clinical trial sized, more data sources to integrate, greater focus on targeting chronic and degenerative diseases, and higher failure rates for drugs tested in earlier-phase clinical trials.

On average, it takes more than 10 years and $2.6 billion to research and develop a new medicine[6]. Just 12% of drug candidates that enter clinical testing are approved for use by patients. Policies like that proposed by Governor Lamont could freeze future innovation by discouraging research and development into the hardest to treat conditions, including cancer, neurological conditions like Alzheimer's disease, ALS, Parkinson's, and rare diseases by taking away the incentives that allow manufacturers to invent new medicines.

American patients have faster access to more medicines than patients anywhere else in the world, and doctors and patients work together to decide which medicine is right for them. In countries that use government price controls, patients can access fewer new medicines and face long treatment delays. Nearly 90% of new medicines launched since 2011 are available in the U.S. compared to just 50% in France, 46% in Canada and 41% in Ireland.[7] Even the medicines available in these countries take much longer to reach patients. On average, patients must wait at least 18 months longer in France,

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2 BRG: The Pharmaceutical Supply Chain 2013-2020. January 2022.

3 IQVIA. "Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025." Published May 2021.

4 IQVIA Institute for Human Data Science. Medicine spending and affordability in the United States. Published August 2020. Accessed August 2020. https://www.iqvia.com/insights/theiqvia-institute/reports/medicine-spending-and-affordabilityin-the-us

5 *BIO v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007),

6 Tufts Center for the Study of Drug Development

7 The Catalyst, Setting the record straight on international reference pricing. July 19, 2019. Available at https://catalyst.phrma.org/setting-the-record-straight-on-international-reference-pricing.

15 months longer in Canada, and 20 months longer in Ireland than in the U.S.
In addition to a real impact on access and innovation, this legislation could have a significant impact on Connecticut's economy where the bioscience industry supports $9 billion in economic output and over 35,000 jobs.

A state importation program would risk patient safety, is unlikely to produce significant cost savings and fails to recognize the additional resources needed to implement and maintain an importation program.

In September 2020, the U.S. Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) issued its final rule (the Final Rule) implementing a provision of federal law allowing the commercial importation of certain prescription drugs from Canada through FDA-authorized, time-limited programs sponsored by states or Indian tribes. The Secretary concurrently offered "certification" that the program would pose no additional risk to the public's health and safety and would result in a significant reduction in the cost to the American consumer as required by law. The Rule provided no proof that importation programs will not provide additional risk to public health and safety or result in significant cost savings. Instead, the federal government placed the responsibility of ensuring public safety and proving significant cost savings on the states.

The Federal Rule places the onus on states to prove "significant cost savings" from a state importation program (SIP) and acknowledges that "SIP Sponsors will face costs to prepare proposals, implement authorized programs, and produce records and program reports."[i] Extensive state resources are required for the implementation and administration of an importation program including but not limited to:

- ***Start-up and Ongoing Costs:*** A state importation program would ultimately assign numerous new responsibilities to the State of Connecticut, including: the design of the importation program; compliance with existing federal laws, including track and trace; development of a wholesale prescription drug importation list; and ongoing administrative costs.

- ***Compliance with Federal Law:*** Both the Foreign Seller and the Importer, under supervision of the state, will be subject to the supply chain security requirements set forth in the Final Rule and under the federal Food, Drug & Cosmetic Act (FD&C Act).

- ***Law Enforcement Costs:*** In July 2017, the National Sheriffs Association approved a resolution opposing state importation legislation because such programs would "jeopardize law enforcement's ability to protect the public health, threaten the safety of our (U.S.) drug supply, and endanger law enforcement officers, their canines, and other first responders."[ii] As former FBI director Louis J. Freeh recently wrote, "the sheer strain that legalized drug importation would have on law enforcement agencies cannot go unappreciated…[W]e've also been faced with resource and budget challenges that force us to do more with less. Rolling the dice on a drug importation law would undoubtedly take resources away from other important law enforcement efforts."[iii]

- ***Public and Stakeholder Education:*** Any statewide prescription drug program requiring voluntary participation from supply chain entities and consumers will require training and education.

In public comments to the FDA during the rulemaking process, several states that passed importation laws expressed concern with the ability to recoup state costs, prove significant savings, achieve appropriate levels of access, and operate efficiently under the parameters outlined in the proposed rule. The Final Rule failed to address these concerns. The Colorado Joint Budget Committee approved their state's Department of Health Care Policy and Financing's FY 2020-21 recommendation to delay of the implementation of Colorado's Canadian importation program in light of budget concerns. After conducting a study on the feasibility of importation, the state of Wyoming determined in September 2020 that a state drug importation program would likely not create significant savings and would be unsustainable in the long-term.

This legislation could increase the risk to consumer health and safety by weakening the prescription drug closed supply chain and opening Connecticut to increased criminal activity.

Opening our closed distribution system to importation would gravely compromise the integrity and safety of the U.S. prescription drug supply. Importation presents a huge opportunity for unscrupulous suppliers and/or criminal organizations to increase the flow of substandard, adulterated or counterfeit drugs – including pills laced with deadly fentanyl – into the U.S. FDA is the gold standard in ensuring the safety and effectiveness of medicines for the U.S.

market and importation would have the same effect as repealing current FDA and consumer protections.

The legislation fails to acknowledge the complexities of setting up a state importation program that adequately protects public health and safety. Specifically, it fails to acknowledge the challenges associated with adherence to the federal "track and trace" system established under the Drug Supply Chain Security Act (DSCSA) and the inherent risk to public safety if it is compromised. Both the draft legislation and the federal Rule place significant responsibility on states to adhere to federal track and trace requirements and demonstrate that any importation program would pose no additional risk to public health.

In 2013, Congress unanimously enacted bipartisan legislation to address concerns of unsafe and counterfeit drugs entering the U.S. pharmaceutical supply chain. The Drug Supply Chain Security Act (DSCSA) established an electronic system to uniquely identify each package of drugs and trace those packages as they are distributed. Through the DSCSA and prior actions, the U.S. has established one of the most secure supply chains in the world and ensures proper protection of patients. Drug importation programs severely undercut the protections of the DSCSA, compromising patient safety. If Connecticut pursues an importation program, it will assume significant risk and potential cost in an effort to ensure public safety.

Canadian law does not prohibit the transshipment of drugs from any country—including those in the third world—into Canada and then into the United States, heightening concerns about the safety and reliability of these medicines. The FDA determined that 85 percent of the drugs sold by supposedly Canadian pharmacies come from 27 countries other than Canada.[iv] PhRMA shares a desire to address patient affordability within the health care system and reduce consumer costs in the State of Connecticut. However, for the reasons stated above, we do not believe development of a drug importation program will produce the desired results and could significantly jeopardize patient safety.

PhRMA recognizes the access challenges faced by patients in Connecticut with serious diseases. **However, this legislation could limit the treatments available to patients and stifle innovation.** PhRMA stands ready to work with the legislature to develop market-based solutions that help patients better afford their medicines at the pharmacy counter. **For these reasons, we respectfully oppose SB 13**

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested more than $1 trillion in the search for new treatments and cures, including $91.1 billion in 2020 alone.

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[i] https://www.hhs.gov/sites/default/files/importation-final-rule.pdf

[ii] Drug Enforcement Administration (undated; viewed on July 25, 2017), DEA Warning to Police and Public: Fentanyl Exposure Kills, https://ndews.umd.edu/sites/ndews.umd.edu/files/DEA%20Fentanyl.pdf. Also, Drug Enforcement Administration (July 2016), supra.

[iii] Louis J. Freeh op-ed, "Cost of drug importation could unfairly shift to law enforcement," The Philadelphia Inquirer, May 5, 2017.

[iv] FDA. "FDA Operation Reveals Many Drugs Promoted as "Canadian" Products Really Originate From Other Countries." December 2005